EXHIBIT A

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Food and Drug Administration
Division of Freedom of Information
5630 Fishers Lane
Room-1035
Rockville, MD 20857

Request Pursuant to Freedom of Information Act

Dear Sir/Madam:

We write to submit a request pursuant to the Freedom of Information Act and relevant statutes and regulations, including but not limited to 21 C.F.R. §§ 20.2 & 20.23. The following requests for information are being made on behalf of Boston Scientific Corporation in conjunction with pending litigation brought by Steven L. Higgins, M.D., against Boston Scientific, in the case styled as *U.S. ex rel. Steven Higgins v. Boston Scientific Corp.*, Civil Case No. 11-cv-2453 (D. Minn.), which is a *qui tam* action initiated by Dr. Higgins under the federal False Claims Act and in which the United States declined to intervene. In this case, Dr. Higgins alleges that Boston Scientific concealed information regarding defects in the products known as Cognis and Teligen in order to procure FDA's approval of the products and later to avoid and then limit the impact of a recall related to these products.

The following requests seek information that is relevant to this lawsuit concerning (1) an interview of Steven L. Higgins, M.D., on April 13, 2010 at Scripps Memorial Hospital in La Jolla, California at or about 10:20 AM, that was conducted by Scott K. Zika, FDA Consumer Safety Office and Robert S. Sweeton, FDA Consumer Safety Office (hereafter, the "2010 Investigation"); (2) copies of information provided by Dr. Higgins and others to FDA in the course of the 2010 Investigation and/or any additional investigation concerning purported defects, recalls of the Cognis and Teligen products, as well as their compliance with FDA rules and requirements (3) FDA's final conclusions and determinations concerning the adequacy of information submitted to FDA by Boston Scientific in connection with Boston Scientific's U.S. launch of its Cognis and Teligen products, including the extent of FDA's knowledge about purported defects of those products that were discovered during and after the European launch of those products; and (4) FDA's final conclusions and determinations concerning the adequacy of Boston Scientific's 2009 recall of the Cognis and Teligen products.

Accordingly, and pursuant to the agency's regulations requiring submission of requests consistent with the provisions of the Freedom of Information Act, we hereby request the following categories of documents:

1. All FDA Form 482 documents relating to the investigation that included an interview of Steven L. Higgins, MD, on April 13, 2010 at Scripps Memorial Hospital in La Jolla, California at or about 10:20 AM, by Scott K. Zika, FDA Consumer Safety Office and Robert S. Sweeton, FDA Consumer Safety Office (hereafter, the "2010 Investigation"). Dr. Higgins has disclosed the Form 482 corresponding to his interview, as well as electronic correspondence preceding that interview in which Mr. Zika indicated an interest in discussing Dr. Higgins' awareness of any product quality problems encountered during pacemaker implantation or any product quality problems that would necessitate explantation of pacemakers. Dr. Higgins has thus generally described his interview on April 13, 2010 and his vague understanding of the purpose of the 2010 Investigation, but his memory of the interview and discussions with Mr. Zika and/or Mr. Sweeton were very limited.

2. Documents relating to the 2010 Investigation, including but not limited to documents concerning Boston Scientific Corporation (including but not limited to its predecessor, Guidant Corporation) and its Cognis and/or Teligen products; transcripts or notes of interviews relating to Boston Scientific/Guidance and Cognis/Teligen; and documents reflecting facts, information, and data provided to FDA in any format (including verbally) during the 2010 Investigation.

3. Documents reflecting the purpose of the 2010 Investigation, and the basis for initiating the 2010 Investigation, including without limitations notes, memoranda, and reports by Mr. Zika, Mr. Sweeton, or other FDA personnel.

4. Documents provided to Mr. Zika, Mr. Sweeton, and/or FDA during the 2010 Investigation concerning Boston Scientific Corporation (including but not limited to its predecessor, Guidant Corporation) and its Cognis and/or Teligen products, including without limitation documents provided by Dr. Higgins and Boston Scientific/Guidant.

5. Documents reflecting final determinations or conclusions reached by Mr. Zika, Mr. Sweeton, and/or FDA concerning Boston Scientific Corporation (including but not limited to its predecessor, Guidant Corporation) and its Cognis and/or Teligen products in connection with the 2010 Investigation, including closing memoranda, final dispositions, and/or communications reflecting decisions to conclude the 2010 Investigation and reasons therefor.

6. To the extent not otherwise covered by Request Nos. 1-5 immediately above, documents reflecting communications between FDA and Boston Scientific Corporation (including but not limited to its predecessor, Guidant Corporation) concerning defects, recalls, or actual or potential compliance (or lack thereof) of the Cognis and/or Teligen products with FDA rules, procedures, or regulations.

7. To the extent not otherwise covered by Request Nos. 1-6 immediately above, documents containing or reflecting FDA conclusions, determinations, discussions, and decisions concerning the adequacy of the July 2009 recalls of the Boston Scientific/Guidant Cognis and/or Teligen products.

8. To the extent not otherwise covered by Request Nos. 1-7 immediately above, documents containing or reflecting FDA conclusions, determinations, discussions, and decisions concerning the adequacy of the information supplied to or otherwise available to FDA in connection with the July 2009 recalls of the Boston Scientific/Guidant Cognis and/or Teligen products.

9. To the extent not otherwise covered by Request Nos. 1-8 immediately above, documents containing or reflecting FDA conclusions, determinations, discussions, and decisions concerning the adequacy of the information supplied to or otherwise available to FDA prior to product approval of the Boston Scientific/Guidant Cognis and Teligen products, relating to alleged adverse events and/or purported product defects discovered during the European launch of those products.

As noted above, these requests for information are targeted to obtain clarity concerning the 2010 Investigation, FDA's final conclusions and determinations concerning the adequacy of Boston Scientific's 2009 recall of the Cognis and Teligen products, and to obtain copies of information provided by Dr. Higgins and others to FDA in the course of the 2010 Investigation and/or any additional investigation concerning purported defects, recalls of the Cognis and Teligen products, as well as their compliance with FDA rules and requirements. Significantly, FDA is the only entity with access to the relevant information sought in these requests, and Boston Scientific does not have any alternative source from which to seek the relevant information, as confirmed by Dr. Higgins' deposition testimony that he does not recall the substance of the discussion or information he may have provided to FDA during the course of the 2010 Investigation, and further because Dr. Higgins did not know the purpose or other details relating to the 2010 Investigation or any of the other topics described in these Requests.

Moreover, it is in the best interests of FDA, as well as the United States generally, to provide the requested information. Specifically, Dr. Higgins is pursuing his lawsuit in the name of the government and under the *qui tam* provisions of the federal False Claims Act, alleging generally that Boston Scientific failed to adequately disclose information to FDA concerning issues with the Cognis and Teligen products which became the subjects of the U.S. launch of Cognis and Teligen, as well as the subsequent 2009 recalls. Accordingly, it is crucial to have an accurate and complete record, to the extent reasonably possible, concerning the topics addressed in the Requests above. Indeed, FDA's view about the information available to it concerning potential issues with the Cognis and Teligen devices, and its determinations concerning the adequacy of Boston Scientific's disclosures of information about those devices, are of vital importance to ensuring that allegations and characterizations concerning FDA's views are properly considered and accurately portrayed in light of facts, documents, and evidence from FDA itself. Moreover, because the 2010 Investigation has closed, and further because FDA's determinations concerning the July 2009 recalls became final agency decisions almost a full decade ago, FDA's production of the requested information does not raise any material risk of an undue impact on the agency or its activities. Furthermore, to the extent Boston Scientific was a subject of the 2010 Investigation, and its products were the subject of the 2009 recalls, and Dr. Higgins has initiated this action in the name of the agency and the federal government, there is no risk that any of the requested information will infringe upon confidentiality expectations, particularly since Dr. Higgins' allegations have put these specific topics directly at issue in the litigation. Accordingly, FDA's

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disclosure of the requested information is in the bests interests of the agency and further is in the interests of ensuring the accuracy of claims raised on FDA's behalf.

Boston Scientific is willing to pay reasonable fees for production of documents responsive to the requests above, up to $1,000. If production of responsive documents will generate costs in excess of $5,000, please contact undersigned counsel immediately to discuss the nature and amount of costs required to provide all responsive documents.

Thank you in advance for your consideration. If you have any questions about these requests, please contact us at (202) 414-9200.

Very truly yours,

Rick Robinson
Andrew C. Bernasconi

RR:od